Public Health Action

International Union Against Tuberculosis and Lung Disease

Health solutions for the poor

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VOL 11 NO 3 PUBLISHED 21 SEPTEMBER 2021

Challenges in LTBI care in the United States identified using a nationwide TB medical consultation database

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http://dx.doi.org/10.5588/pha.21.0026

BACKGROUND: Identifying and treating individuals with latent TB infection (LTBI) represents a critical and challenging component of national TB elimination. Medical consultations by the Centers for Disease Control and Prevention (CDC) funded TB Centers of Excellence (COEs) are an important resource for healthcare professionals (HCPs) caring for individuals with LTBI. This study aimed to identify the most common clinical concerns regarding LTBI care and to describe epidemiologic and clinical features of patients discussed in these consultations.

METHODS: This mixed-methods study randomly sampled 125 consultation inquiries related to LTBI from the COEs' medical consultation database in 2018. Text from consultation records were reviewed and coded to identify reasons for the inquiries and common epidemiologic and clinical patient characteristics.

RESULTS: The most common topics of inquiry for consultation included accurate LTBI diagnosis (36%), management of LTBI treatment-related issues (22%), and choice of appropriate LTBI treatment regimen (17%). Patients for whom consultations were requested commonly had another medical condition (34%), were non-U.S. born (31%), were children (25%), and had a history of travel to TB-endemic areas (18%).

CONCLUSION: Our findings emphasize the challenge of managing patients with either suspected or confirmed LTBI, highlighting the need for ongoing medical consultation support for nuanced clinical and epidemiologic scenarios.

B remains a devastating global health epidemic, with 10 million incident cases and 1.4 million deaths reported in 2019.1 Although U.S. TB rates have declined, 8,920 new TB cases were reported in 2019.2 Furthermore, an estimated 20-25% of the global population^{3,4} and 4–5% of the U.S. population^{5,6} have latent TB infection (LTBI), defined as persistent Mycobacterium tuberculosis infection maintained under immune control without clinical or radiographic evidence of TB.7 Infection can be detected using the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA),8 and effective treatment regimens have been established.9 The Council of State and Territorial Epidemiologists includes this laboratory criteria in its case definition of confirmed LTBI, which requires clinical criteria, laboratory criteria, and the failure to isolate M. tuberculosis from a clinical specimen if collected. 10 Prevention of TB disease through identification and treatment of LTBI is critical for TB elimination. 1-5

In the United States, most states do not mandate complete LTBI reporting, and many health care providers (HCPs) are unaware of current LTBI diagnostic and treatment recommendations.5,7,11 Other challenges to LTBI testing and treatment across the LTBI cascade broadly include 1) screening and testing individuals with high TB risk; 2) provision of safe and effective treatment; 3) minimizing adverse events (AEs); 4) ensuring treatment completion; and 5) evaluating outcomes. 12,13 To improve the capacity for TB prevention, the Centers for Disease Control and Prevention (CDC) has funded state and local TB programs, as well as regional TB Centers of Excellence (COEs) for over a decade. TB programs and COEs provide training, education, and medical consultation for managing patients with TB and support programmatic activities to strengthen TB elimination efforts.14 Beginning in 2006, COEs began recording consultations in an electronic medical consultation database (MCD).

The primary objective of this study was to evaluate COE consultations captured from the MCD to identify common clinical challenges and potential provider knowledge gaps throughout the LTBI cascade. The secondary objective was to describe epidemiologic and clinical features of patients discussed in these consultations.

METHODS

Study design and sample selection

All consultations entered into the MCD system from January 1 to December 31, 2018 under the categories "LTBI" and "TST/IGRA" were eligible for inclusion. Applying a mixed-methods approach, we randomly sampled 125 consultations stratified by occupation of the HCP and used key words and themes in the text of TB COE consultations to analyze the sample.

Quantitative analysis

The characteristics of HCPs requesting TB COE consultation were described quantitatively, including their occupation, work setting, and city or state of practice. To validate the stratified sample of 125 consults and demonstrate its representativeness of all consultations from 2018, Z-test analysis was used to compare distributions of characteristics of the sample to all eligible consultations from 2018 (P < 0.05). For this analysis, variables were dichotomized as 1) physician vs. nurse/other (epidemiologists, physician-extenders, etc.), and 2) public health care setting (state, regional and local public health departments) vs. other (academic insti-

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ACKNOWLEDGEMENTS

Services described in this report were supported by funding from CDC RFA PS-15–501.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

KEY WORDS

latent tuberculosis infection; public health; TB Centers of Excellence; medical consultations

Received 7 April 2021 Accepted 1 July 2021

PHA 2021; 11(3): 162–166 e-ISSN 2220-8372

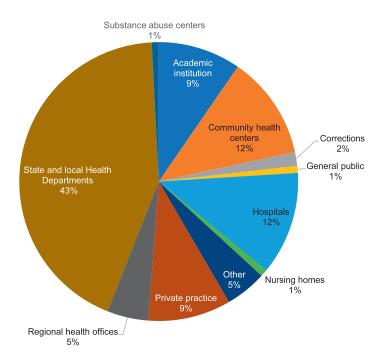


FIGURE Occupation and occupation setting of HCP requesting consultations to CDC TB Centers of Excellence, 2018. HCP = health care provider; CDC = Centers for Disease Control and Prevention.

tutions, private practice, correctional facility, etc.). Quantitative analysis was performed using MS Excel (Microsoft, Redmond, WA, USA).

Oualitative analysis

A primary investigator reviewed and coded the free text of the inquiry and response for each of the 125 consultations. Themes or key words were identified and categorized to achieve two specific objectives: 1) to identify reason(s) for each consultation, and 2) to identify common clinical and epidemiologic factors that characterized the patient(s) being discussed. To assess coding reliability, a second investigator coded a subset of 30 inquiries from the same sample and coding concordance was assessed. Two investigators together reviewed discordant results and sought consensus. A third investigator was assigned to arbitrate if consensus was not achieved. Qualitative analysis was performed using NVivo v12 (QSR International, Burlington, MA, USA).

Institutional review board approval

Rutgers University Institutional Review Board, New Brunswick, NJ, USA, approved this study and CDC determined it to be a program evaluation and not human subjects research.

RESULTS

Characteristics of HCPs requesting consultation from TB COE

A total of 557 consultations provided in 2018 fit study inclusion criteria. From these 557 consultations, 125 were randomly chosen and analyzed. Of the 125, the vast majority were requested by physicians (45%) and nurses (49%). Requests were made from 11 different healthcare settings (Figure); 60 (48%) were from state, regional and local public health settings and 65 (52%) from other healthcare facilities. There were 12 (9%) consultations from private practices, 15 (12%) from hospitals, 15 (12%) from community health centers, 12 (10%) from academic institutions, and 2 (2%) from correctional facilities. Consultation requests came from 30 different cities and states throughout the United States, with nearly half of the sample comprised from Texas (25%) and California (23%).

Reasons for TB COE consultations

There were 149 questions asked in the 125 consultations sampled; 17 consultations included more than one question. Consultation questions were organized under five categories following the se-

 TABLE 1
 Reasons for medical consultation inquiries from US healthcare providers to CDC TB Centers of Excellence, 2018

Category	Focus of the consult question	(n = 149) n (%)
LTBI diagnosis		53 (36)
General	Whether clinical findings are consistent with LTBI and should be further evaluated	31 (21)
Radiology	Whether radiographic findings support LTBI diagnosis and appropriate patient management	8 (5)
Discordant immunologic testing	Discordance in immunologic testing (between TST and IGRA)	14 (11)
Other treatment-related topics		33 (22)
Adverse events	Evaluation and management of a possible adverse reaction during LTBI treatment	10 (7)
Completion of treatment	Whether a patient has completed a full course of LTBI treatment	3 (2)
Medication dosage	The appropriate dose of LTBI medication	9 (6)
Drug interactions	Potential interactions between LTBI medication(s) and another medication that a patient is prescribed	9 (6)
Patient attitudes towards LTBI therapy	How to manage a patient who does not accept or declines LTBI treatment	2 (1)
Choice of treatment regimen	Which is the most appropriate LTBI treatment regimen for a patient?	26 (17)
Screening for TB risk		21 (14)
Screening high-risk persons	How or when to screen other high-risk persons for TB risk	18 (12)
Contact investigation	Identification and management of contacts of a person with TB disease	3 (2)
Other		16 (11)
Miscellaneous	Other LTBI issues not included in the categories above	11 (7)
Ambiguous	Reason for consultation is not clear	3 (2)
Not LTBI-related	Consultation not related to LTBI or TST/IGRA (likely miscategorized in the MCD)	1 (1)
Duplicate	Consultation was duplicate of a previous entry	1 (1)

TABLE 2 Most common characteristics of the patients discussed in consultations to the CDC TB Centers of Excellence, 2018

Characteristic	(n = 125) n (%)
Underlying chronic illness	42 (34)
Born outside the United States	39 (31)
Pediatric (age ≤ 18 years)	31 (25)
Foreign travel	23 (18)
Exposure to immunosuppressive medications	12 (10)
BCG vaccine exposure	12 (10)
Health care worker	10 (8)
Pregnant	9 (7)
Possible MDR- or XDR-TB exposure	9 (7)
HIV infection	6 (5)
Renal-related pathology	5 (4)
Rheumatologic disease	4 (3)
Inflammatory bowel disease	3 (2)
Oncologic	3 (2)

CDC = Centers for Disease Control and Prevention; BCG = bacilli Calmette-Guérin; MDR-TB = multidrug-resistant TB; XDR-TB = extensively drug-resistant TB.

quence of the LTBI cascade (Table 1): 1) TB screening activities (14%) such as contact investigation or other high TB risk patient screening; 2) LTBI diagnosis (36%), including clinical factors, radiography, and discordant TB screening tests; 3) choice of LTBI treatment regimen (17%); 4) other treatment-related topics (22%), including treatment completion, medication dosage, AEs, and patient attitudes towards LTBI treatment; and 5) other topics (11%).

Characteristics of patients discussed in TB COE consultations

Review of TB COE consultations identified important clinical and epidemiologic characteristics of patients being discussed (Table 2). Almost a third (31%) were born outside of the United States, and a quarter were children (\leq 18 years). There were 34% with another medical condition (e.g., diabetes, underlying renal or liver disease, substance abuse, etc.). Of 14 patients with reported HIV status, 6 were HIV-positive (5%). Other characteristics included history of foreign travel (18%), treatment with immunosuppressive medications (10%), history of bacilli Calmette-Guérin (BCG) vaccination (10%), work in a healthcare setting (8%), possible exposure to multidrug-resistant TB (MDR-TB), extensively drug-resistant TB (XDR-TB) or pre-XDR-TB (7%), and being pregnant (7%).

Reliability of the coding process

Among the 30 consultations coded by both the primary and secondary investigators, 29 (97%) identified the same reasons for consultation. Consensus was achieved without need for an arbitrator for the one discordant consultation.

Validation of sample

The distribution of characteristics among the study sample (Table 3) were not significantly different from the distribution among all 557 eligible 2018 consultations. Of all the eligible consultations, 286 (51%) were requested by local, regional, and state health departments (P = 0.51) and 233 (42%) were from Texas or California (P = 0.27).

DISCUSSION

To prevent future TB disease, the United States should prioritize the identification and treatment of LTBI among the estimated 13

TABLE 3 Characteristics of HCP requesting consultation from CDC TB COE

Characteristic	(n = 125) n (%)
Occupation	· ·
Physician	56 (45)
Nursing	61 (49)
Other	8 (6)
Occupation setting	· /
Local health department	43 (34)
Community health center	15 (12)
Hospital	15 (12)
Academic institution	12 (10)
Private practice	12 (10)
State health department	11 (9)
Other	6 (5)
Regional health office	6 (5)
Corrections	2 (2)
General public	1 (1)
Nursing home	1 (1)
Substance abuse center	1 (1)
State of practice	4 (4)
Alabama	1 (1)
Alaska	1 (1)
Arizona	2 (2)
California	29 (23)
Connecticut Delaware	2 (2)
Florida	1 (1) 1 (1)
Illinois	3 (2)
Indiana	2 (2)
lowa	2 (2)
Kansas	3 (2)
Kentucky	6 (5)
Maryland (excluding Baltimore)	2 (2)
Massachusetts	3 (2)
Minnesota	1 (1)
Missouri	1 (1)
Montana	1 (1)
Nevada	1 (1)
New Jersey	3 (2)
New York	1 (1)
Ohio	1 (1)
Oregon	6 (5)
Pennsylvania (excluding Philadelphia)	3 (2)
Puerto Rico	1 (1)
South Dakota	2 (2)
Texas	31 (25)
Utah Visasia is	2 (2)
Virginia	6 (5)
Washington Wisconsin	4 (3) 2 (2)
Unknown	2 (2) 1 (1)
Center	1 (1)
Curry International TB Center (CITC)	45 (36)
Heartland National TB Center (HNTC)	42 (34)
Global TB Institute of Rutgers, The State	12 (31)
University of New Jersey (GTBI)	22 (18)
Southeastern National TB Center (SNTC)	15 (12)

HCP = health care provider; CDC = Centers for Disease Control and Prevention; COE = Centers of Excellence; LTBI = latent TB infection.

million infected residents.¹² This study analyzed LTBI clinical consultations performed by COEs to identify common clinical challenges that HCPs face along the LTBI cascade.¹³ It is not surprising that half of study consultations were requested by nurses and that half arose from public health settings. Government public health agencies have legal authority for controlling TB, and nurses play a primary role in LTBI activities from risk-based screening through ensuring treatment completion.¹⁵ U.S. guidelines emphasize public and private health collaboration to target the highest risk populations, including those represented in study consultations (Table 2).¹⁶ Amidst dwindling expertise in TB management, the CDC established TB COEs to build capacity among HCPs in all settings through medical consultation, training, and education provided by national TB experts.¹⁷

Over a third of TB COE consultations discussed challenges in accurately diagnosing LTBI. There is currently no test that can directly detect M. tuberculosis in persons with LTBI. Instead, diagnosis is based on epidemiologic risk, a positive TB screening test (TST or IGRA) and the absence of clinical or radiographic evidence of TB disease. As both screening tests indirectly measure a person's cellular immune response to M. tuberculosis, they cannot be used to distinguish between past and current infection or between LTBI and TB disease.8 Inconclusive or discordant results discussed in 9% of medical consults reviewed here pose a common clinical challenge and are widely reported, particularly among persons with HIV infection,11 healthcare workers,18 immigrants, 19 and children. 20 TST-positive/IGRA-negative discordance may be due to BCG exposure, nontuberculous mycobacteria infection, or delay in IGRA conversion compared to TST.²¹ Explanations for a TST-negative/IGRA-positive discordance are less clear and require further investigation.²²

Almost a quarter of TB COE consultations focused on LTBI treatment-related topics, including treatment completion, medication dosage, AEs, and patient attitudes towards LTBI treatment. In a systematic review and meta-analysis of study-level observational data, Alsdurf et al. found that only a minority of persons (19%) with presumed LTBI completed treatment.¹³ This underscores the importance of efforts to encourage LTBI treatment uptake and completion of therapy that must accompany efforts to scale up screening and testing among populations at high risk. Also discussed in 7% of study consults, effective management of AEs during treatment can ensure patient safety and improve treatment tolerance to enable completion.²³ Although patient perspectives regarding taking LTBI therapy comprised a minimal portion of TB COE consults, other studies have demonstrated that patient's knowledge, attitudes and beliefs can negatively influence LTBI treatment adherence and should be considered.²⁴

Choosing the appropriate LTBI treatment was the focus of 17% of TB COE consultations. Newer rifamycin-based regimens have replaced 9 months of isoniazid (INH) as standard LTBI treatment in adults and children given their shorter duration enabling improved adherence, low rate of toxicity, and greater or equal effectiveness. Recent guidelines preferentially recommend 3 months of once-weekly INH plus rifapentine (3HP) and 4 months of daily rifampin (4R); although still recommended in certain patients, 3 months of daily INH and rifampin is not commonly used in the United States. Experience with rifampin-based LTBI treatment is increasing, and both 3HP and 4R are cost-effective and convenient options for populations where treatment completion may be a challenge. As national public health efforts are expanding the use of both 3HP and 4R among high-risk individuals and guidelines recommend general use of these regimens, HCPs will

likely become more confident in changing their LTBI treatment practices. $^{26}\,$

This analysis had several limitations. Although we found that characteristics of the sample of 125 consultations analyzed were representative of all 557 LTBI-related TB COE consultations made in 2018, the MCD did not contain sufficient data to fully characterize either the sample or the larger cohort; provider demographics, medical training, and practice experience were not captured, and patient demographics, education, health care literacy level, or social determinants of health were not consistently recorded. We were also not able to compare HCPs who consult TB COEs to those who do not, hindering assessment of study representativeness to all U.S. LTBI providers. Another limitation is that MCD documentation is not standardized and varies substantially among the different COEs and also among different providers at the same COE. Because patient characteristics were collected through qualitative analysis and were not reported in a standardized format, our results may underestimate the frequency of these characteristics. Finally, study consultations were made in 2018, whereas the clinical challenges and HCP practice standards may have changed following the release of new national LTBI guidelines in 2020.9

Recognizing the most common challenges in LTBI care, particularly screening of high-risk groups, accurate LTBI diagnosis, identification of an appropriate LTBI treatment regimen, and effective management of treatment-related challenges, is a valuable step towards clinical practice improvement among U.S. HCPs. Evidence-based guidance should target the clinical challenges described in this study that cause drop off along the LTBI care cascade. Novel tools such as web-based or cellular phone-based applications may enhance patient acceptance and provider management across the LTBI cascade; however, the utilities of these tools need to be further assessed.²⁷ Analysis of TB COE consults and other clinical data occurring after the 2020 U.S. LTBI treatment regimen guidelines were issued can further enhance understanding of persisting challenges for LTBI management. HCPs are encouraged to contact the TB COE in their region (https://www.cdc.gov/ tb/education/tb_coe/default.htm) or state and local TB elimination programs (https://www.cdc.gov/tb/links/tboffices.htm) for assistance with TB or LTBI challenges. This collaborative approach between public health and other providers will improve LTBI diagnosis and care and boost efforts toward national TB elimination.

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CONTEXTE: L'identification et le traitement des personnes atteintes d'infection tuberculeuse latente (LTBI) sont des composantes essentielles et difficiles de la stratégie nationale d'élimination de la TB. Les consultations médicales des TB Centers of Excellence (COE), financés par les Centres pour le contrôle et la prévention des maladies (CDC), sont d'importantes ressources pour les professionnels de santé qui prennent en charge les personnes atteintes de LTBI. Cette étude avait pour objectif d'identifier les problèmes cliniques les plus fréquents en matière de prise en charge de la LTBI, et de décrire les caractéristiques épidémiologiques et cliniques des patients évoquées lors de ces consultations.

MÉTHODES: Cette étude à méthodes mixtes a sélectionné de manière aléatoire 125 demandes de consultations relatives à la LTBI à partir de la base de données des consultations médicales du COE en 2018. Les notes des dossiers de consultation ont été

revues et codées pour identifier les raisons des demandes, ainsi que les caractéristiques cliniques et épidémiologiques fréquentes des patients.

RÉSULTATS: Les raisons les plus fréquentes de demandes de consultation étaient diagnostic précis de LTBI (36%), prise en charge des problèmes liés au traitement de la LTBI (22%) et choix d'un schéma thérapeutique approprié de la LTBI (17%). Les patients pour lesquels des consultations étaient demandées avaient fréquemment une autre pathologie (34%), n'étaient pas nés aux États-Unis (31%), étaient des enfants (25%) et avaient des antécédents de voyage dans des zones où la TB est endémique (18%).

CONCLUSION: Nos résultats mettent l'accent sur les défis de la prise en charge des patients avec une LTBI présumée ou confirmée, soulignant le besoin d'aide continue aux consultations médicales pour des scénarios épidémiologiques et cliniques nuancés.

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